IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF LOUISIANA
SHREVEPORT DIVISION

AMBER RUTLAND,

Plaintiff,

v.

JANSSEN PHARMACEUTICALS, INC. and JOHNSON & JOHNSON CO.

Defendants.

Civil Action No. 5:16-cv-666

JUDGE MAURICE HICKS, JR.

MAGISTRATE JUDGE KAREN HAYES

FIRST AMENDED COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff, AMBER RUTLAND, brings this case against Defendants for injuries suffered as a direct result of Plaintiff's ingestion of the pharmaceutical product INVOKANA. Plaintiff alleges as follows:

NATURE OF THE CASE

1. This is an action for damages suffered by Plaintiff as a direct and proximate result of Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of INVOKANA (at times referred to herein as "the subject product") for the treatment of diabetes.

2. Defendants Janssen Pharmaceuticals ("JANSSEN"), and Johnson & Johnson, Co. ("JOHNSON & JOHNSON") concealed, and continue to conceal, their knowledge of INVOKANA's unreasonably dangerous risks from Plaintiff, other consumers, and the medical community.

3. As a result of the defective nature of INVOKANA, persons who were prescribed and ingested INVOKANA, including Plaintiff, have suffered and may continue to suffer severe and permanent personal injuries, including diabetic ketoacidosis, stroke, heart attack, and severe kidney damage.

4. After beginning treatment with INVOKANA, and as a direct and proximate result of Defendants' actions and inaction, Plaintiff developed kidney failure and other injuries. Plaintiff's ingestion of the defective and unreasonably dangerous drug INVOKANA has caused and will continue to cause injury and damage to Plaintiff.

5. Plaintiff brings this action for personal injuries suffered as a proximate result of being prescribed and ingesting INVOKANA. Plaintiff accordingly seeks compensatory and punitive damages, monetary restitution, and all other available remedies as a result of injuries caused by INVOKANA.

PARTIES

6. Plaintiff AMBER RUTLAND is a citizen and resident of the State of Louisiana.

7. Plaintiff AMBER RUTLAND began taking INVOKANA on or about April, 2014, and continued to use INVOKANA until May, 2014.

8. Defendant JANSSEN is a Pennsylvania corporation with its principal place of business at 1125 Trenton Harbourton Road, Titusville, New Jersey, and is a wholly owned subsidiary of Defendant JOHNSON & JOHNSON. JANSSEN is registered to do business in Illinois, and has designated a registered agent in Illinois. JANSSEN is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling marketing, and introducing into interstate commerce (including into Louisiana and this District),

either directly or indirectly through third parties or related entities, its products, including the prescription drug INVOKANA.

9. Defendant JOHNSON & JOHNSON is a New Jersey corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey. JOHNSON & JOHNSON is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling marketing, and introducing into interstate commerce (including into Louisiana and this District), either directly or indirectly through third parties or related entities, its products, including the prescription drug INVOKANA.

JURISDICTION

10. This Court has jurisdiction pursuant to 28 U.S.C. § l332(a) because Plaintiff and Defendants are citizens of different States and the amount in controversy exceeds $75,000 exclusive of interest and costs.

11. Venue in this action properly lies in this judicial district pursuant to 28 U.S.C. §l391(a) because Plaintiff resides in this district and because a substantial part of the acts and/or omissions giving rise to these claims occurred within this district.

FACTUAL BACKGROUND

12. This case involves the prescription drug Invokana, which is manufactured, sold, distributed and promoted by the Defendants JANSSEN and JOHNSON & JOHNSON as a treatment for Type 2 Diabetes Mellitus.

13. Defendant JANSSEN, a wholly owned subsidiary of JOHNSON & JOHNSON, acquired the marketing rights to INVOKANA in North America, and marketed, advertised, distributed, and sold INVOKANA in the United States, including in the State of Louisiana.

14. As of 2012 there were approximately 29.1 million Americans who had diabetes and 28 million Americans within that group who have Type II diabetes.[1] Over time, high blood sugar levels can increase the risk for serious complications, including heart disease, blindness, nerve and kidney damage.

15. There are many prescription medication options for Type II diabetes. The first drug generally prescribed for Type II diabetes patients is metformin. Metformin was the first diabetes drug approved by the FDA and is still the most prescribed drug treatment option available today. Metformin works by improving the patient's sensitivity to insulin so the body uses insulin more effectively.

16. Along with Metformin, several other drug classes are available today as treatment options to patients who have Type II diabetes. Some examples of these other drug classes are sulfonylureas, including Glucotrol (generic: glipizide) and Amaryl (glimepiride); meglitinides, including Prandin (repaglinide) and Starlix (nateglinide); thiazolidinediones, including Avandia (rosiglitazone) and Actos (pioglitazone); DPP-4 inhibitors, including Januvia (sitagliptin) and Tradjenta (linagliptin); and GLP-1 receptor agonists which include Byetta (exenatide) and Victoza (liraglutide).

17. Type II diabetes drugs generally reduce blood sugar by eliminating some of the sugar in your blood (GLP-1 receptor agonists, DPP-4 inhibitors), making the body more sensitive to insulin (thiazolidinediones and metformin), or helping the patient's body secrete more insulin (sulfonylureas and meglitinides).

[1] The Center for Disease Control and Prevention's 2014 National Diabetes Statistics Report; http://www.cdc.gov/media/releases/2014/p0610-diabetes-report.html, last accessed on October 5, 2016.

18. Because diabetes is a chronic disease, diabetes drugs are designed for long-term use. Patients have been known to take one drug for many years before being prescribed a different drug. With such long-term use, comes a similar focus on long-term safety. Being able to safely use a diabetes drug along with knowledge about effects of cumulative dosage is paramount with these drugs. In its QuarterWatch publication for the second quarter of 2014, the Institute for Safe Medication Practices ("ISMP") stated "[a] common-sense criterion for diabetes drugs is that they should reflect inherently low risks since it takes years for either progression of the disease or possible but yet-unproven benefits of treatment to be manifest."[2]

19. Defendants submitted their New Drug Application for Invokana on May 31, 2012.

20. Invokana was the first in a new class of Type II diabetes drugs called sodium glucose co-transporter 2 ("SGLT-2") inhibitors. SGLT-2 inhibitors introduced a novel way to control Type II diabetes by involving the kidneys in the process of reducing the patient's blood sugars.

21. SGLT-2 is a protein in humans that facilitates glucose reabsorption in the kidneys. SGLT-2 inhibitors reduce blood sugar levels by reducing glucose reabsorption through the user's kidneys and increasing glucose excretion through the user's urine.

22. Invokana works by blocking the reabsorption of glucose by the kidney, increasing glucose excretion, and lowering blood glucose levels in diabetics who have elevated blood glucose levels.

[2] Institute for Safe Medicine Practices, *QuarterWatch: Monitoring FDA MedWatch Reports*, May 6, 2015 – Data from 2014 Quarter 2, Available online at http://www.ismp.org/QuarterWatch/pdfs/2014Q2.pdf, last accessed October 5, 2016.

23. According to Janssen's own website, "INVOKANA® works with your kidneys to help you lose some sugar through the process of urination."[3]

24. However, SGLT2 inhibitors, including Invokana, are designed to inhibit renal glucose reabsorption with the goal of lowering blood glucose. As a result, excess glucose is not metabolized, but instead is excreted through the kidneys of a population of consumers already at risk for kidney disease.

25. Though Invokana is indicated for only improved glycemic control in type 2 adult diabetics, Defendants have marketed and continued to market Invokana for off label purposes, including but not limited to weight loss, reduced blood pressure, and improved glycemic control in type 1 diabetics.

26. Since Invokana's release, the FDA has received a significant number of reports of diabetic ketoacidosis among users of Invokana.

27. An analysis of the FDA adverse event database shows that patients taking Invokana are several times more likely to report diabetic ketoacidosis than those taking non-SGLT2 diabetes drugs to treat diabetes.

28. Invokana's safety and effectiveness were evaluated in nine clinical trials involving over 10,285 patients with Type II diabetes. The trials showed improvement in hemoglobin A1c levels (a measure of blood sugar control) and fasting plasma glucose (blood sugar) levels.

29. As part of the approval of Invokana, FDA required Janssen Pharmaceuticals to conduct a separate clinical trial to assess a signal of a serious risk of major adverse

[3] https://www.invokana.com/about-invokana/how-invokana-works last visited October 5, 2016.

cardiovascular events with antidiabetic medications, including Invokana. FDA required Janssen to complete two double blind studies to evaluate the cardiovascular risk.

30. Responsive information to FDA's request for Defendants to investigate the cardiovascular risk of Invokana was provided during a January 10, 2013 meeting of the FDA Endocrinologic and Metobolic Drugs Advisory Committee. During that meeting, testimony from a statistical assessment of the cardiovascular safety of Invokana revealed that researchers found a hazard ratio of 6.49 for cardiac events during the first 30 days of the Canagliflozin Cardiovascular Assessment Study ("CANVAS"), a study sponsored by Defendant Janssen Pharmaceuticals. Stated another way, Defendants' own study found that patients on Invokana had a 649% higher probability of suffering a cardiovascular event in the first 30 days of use than did patients who were on the placebo.

31. FDA required Defendants to continue their CANVAS study and continue investigating the proclivity of cardiovascular events and reduction of kidney function from use of Invokana. Defendants' CANVAS study is anticipated to be completed in June, 2017.

32. Defendants received final FDA approval for Invokana on March 29, 2013 in oral tablet doses of 100 mg and 300 mg. Invokana's indications for use statement was "[a]s an adjunct to diet and exercise to improve glycemic control in adults with Type II diabetes mellitus."

33. Even though Invokana was not approved until nearly three months into the year, Defendants spent $12 million on advertising for Invokana between January and October 2013, the most money spent marketing any pharmaceutical drug in the United States during that time period.

34. In an effort to increase their market share and distinguish Invokana from other Type II diabetes drugs, Defendants marketed (and continue to market) Invokana off label for weight loss.

35. As discussed above, there are several different types of diabetes drugs on the market. Most of the drugs available have no discernable effect on a patient's weight, and several of these drugs even can cause weight gain. Because weight loss is typically a main component of treatment in Type II diabetes, a Type II diabetes drug that could cause weight loss would be of substantial benefit to patients, healthcare providers, and the manufacturer of that drug.

36. Other diabetes drugs help body metabolize blood sugar but Invokana is designed to have the body urinate sugar out of the system via the kidneys. This forces blood sugar thru the kidneys, overworking the kidneys as there is not a corresponding reduction in blood sugar thru other mechanisms. This constant stream of sugars in the urine overworks the kidneys, leading to eventual failure and ketoacidosis.

37. At all times relevant, Defendants extensively marketed Invokana off label as a weight loss drug to the public and healthcare providers. For example, in the clinical research results section on their website specifically directed to healthcare providers, Defendants included a prominent tab titled "Body Weight Change." The first statement on the tab said "Invokana® monotherapy demonstrated statistically significant reductions in body weight vs. placebo at 26 weeks." Then there was a graph claiming a 2.2% increase in weight loss for those on 100 mg doses (a mean of 5.5 pounds) and a 3.3% increase in weight loss for those on 300 mg doses (a mean of 7.5 pounds).

38. These reductions in weight are not inconsequential. The CDC[4], American Diabetes Association[5], Mayo Clinic[6], and the National Institute of Diabetes and Digestive and Kidney Diseases ("NIDDK")[7] all recommend weight loss as part of Type II diabetes treatment. And statements like, "You don't have to lose a lot of weight to start seeing results. Just losing 10-15 pounds can make a difference," from the same American Diabetes Association website are common knowledge in the diabetes community.

39. On Defendants' website directed to consumers, in a large chart promoting the alleged benefits of Invokana, Defendants claim, "Invokana® is not for weight loss, but may help you lose weight."[8] Again on Defendants Frequently Asked Questions website directed to consumers, the following question is posed: "If INVOKANA® helps my body get rid of some sugar, can it also help me lose weight?" The answer Defendants provide states, "Although INVOKANA® is not a weight-loss medicine, and each person is different, people can experience reduction in weight."[9]

40. Defendants also provided a checklist of questions for a new patient to ask their doctor about Invokana. Many of the questions relate to steering the conversation towards the patient's weight. Questions a prospective patient are supposed to ask their doctor include:

a. Should I consider losing weight? If so, how much?

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[4] http://www.cdc.gov/diabetes/managing/health.html, last accessed on October 5, 2016.
[5] http://www.diabetes.org/living-with-diabetes/recently-diagnosed/where-do-i-begin/weight-loss.htmllast accessed on October 5, 2016.

[6] http://www.mayoclinic.org/diseases-conditions/diabetes/in-depth/diabetes-diet/art-20044295, last accessed on October 5, 2016.
[7] http://www.niddk.nih.gov/health-information/health-topics/weight-control/Pages/default.aspx, last accessed on October 5, 2016.
[8] https://www.invokana.com/about-invokana/what-is-invokana?&utm_source=google&utm_medium=cpc&utm_campaign=Branded&utm_content=Weight+Loss&utm_term=%252Binvokana+%252Bweight+%252Bloss&gclid=CPnA8piZxM8CFUqmNwodELIPtQ&gclsrc=ds, last accessed October 5, 2016.
[9] https://www.invokana.com/about-invokana/faq, last accessed October 5, 2016.

b. What are the most important lifestyle changes I can make to help improve my numbers?

c. What type of exercise is best for me? Are there any forms of exercise I should avoid?

d. How is INVOKANA® different from other types of medications I'm taking/have tried?[10]

41. On information and belief, these direct-to-consumer advertisements are intended to play on the psyche of a Type II diabetes patient, as Type II diabetes patients are generally looking to lose weight to augment their prescription regimen to help control their diabetes.

42. On information and belief, Defendants intend for healthcare providers and the public to see the alleged added benefit of weight loss and choose Invokana over other Type II diabetes drugs, when in fact these alleged weight loss benefits are one of the catalysts to the serious injuries alleged herein.

43. Defendants' website for Invokana claims that over four million prescriptions have been written for Invokana.

44. As a result of their heavy marketing of Invokana, Defendants turned a new drug with zero market share in March 2013 into a drug that did $278 million in sales in the first quarter of 2015.

45. Invokana's sales nearly tripled from $94 million in sales from the first quarter of 2014, and is nearly 40% more than Invokana's sales from the previous quarter of 2014 which totaled $201 million.

46. Defendants' marketing is misleading in that it overstates Invokana's efficacy while downplaying the serious adverse events. Defendants should have and would have

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10 https://www.invokana.com/sites/www.invokana.com/files/DTCDoctorDiscussionGuideV2.pdf, last accessed October 5, 2016.

discovered the risk of serious cardiovascular events, such as myocardial infarctions, through studies prior to Invokana's approval.

47. Along with the above described serious injuries, less than two years after Invokana's approval, multiple pieces of medical literature have linked SGLT-2 inhibitors with increased ketone production, including:

a. Kohei Kaku et al., *Efficacy and safety of monotherapy with the novel sodium/glucose cotransporter-2 inhibitor tofogliflozin in Japanese patients with type 2 diabetes mellitus: a combined Phase 2 and 3 randomized, placebo- controlled, double-blind, parallel-group comparative study*, 13 CARDIOVASCULAR DIABETOLOGY (2014);

b. Sunder Mudaliar et al., *Changes in Insulin Sensitivity and Insulin Secretion with the Sodium Glucose Cotransporter 2 Inhibitor Dapagliflozin*, 16 DIABETES TECHNOLOGY & THERAPEUTICS 137–144 (2014); and,

c. Yutaka Seino, *Luseogliflozin for the treatment of type 2 diabetes*, 15 EXPERT OPINION ON PHARMACOTHERAPY 2741–2749 (2014)

48. Increased ketone production can lead to a serious and potentially deadly disease called diabetic ketoacidosis (also known as DKA).

49. DKA, a subset of ketoacidosis or ketosis in diabetic patients, is a type of acidosis that typically occurs when insulin levels are inadequate to meet the body's basic metabolic requirements. Insulin deficiency leads to formation of free fatty acids due to breakdown of triglycerides and amino acids, which get converted to highly acidic ketone bodies, leading to acidosis. Physical symptoms include nausea, vomiting, and abdominal pain that can progress to cerebral edema, coma, and death. DKA most commonly occurs in patients with type 1 diabetes and is almost always accompanied by high blood sugar levels.

50. The hallmark symptoms for a differential diagnosis of DKA are high blood sugars and having type 1 diabetes. The DKA events that have been linked to SGLT-2 inhibitors

were not typical for DKA because the patients had Type II diabetes and their blood sugar levels, when reported, were only slightly increased compared to typical cases of DKA.

51. This type of DKA is referred to as euglycemic diabetic ketoacidosis, where the patient's blood sugar is below 200 mg/dl when diagnosed.

52. After approval of Invokana, the FDA received multiple adverse event reports linking Invokana with DKA. Specifically, the FDA received 20 adverse event reports of ketoacidosis in patients treated with SGLT-2 inhibitors from March, 2013 to June 6, 2014, and the FDA continues to receive additional adverse event reports post-June 2014.

53. As a result of the adverse event reports linking Invokana with DKA, and little more than two years after Invokana's approval, on May 15, 2015 FDA issued a safety communication to the public and the medical community that identified SGLT-2 inhibitors as a cause of DKA. This safety communication put particular emphasis on Invokana. The FDA indicated it was continuing to investigate the safety issue.

54. As the manufacturers of Invokana, Defendants knew or should have known that Invokana use was associated with ketoacidosis. Instead, Defendants promoted, and continue to promote, Invokana as a safe and effective treatment for Type II diabetes.

55. Case reports from Invokana's own clinical trials showed the link between Invokana and elevated ketones. At least 4 cases of ketoacidosis or heightened ketones were present in Defendants' submissions to the FDA. Because of how rare an event DKA is in patients with Type II diabetes, a reasonable and prudent manufacturer would have investigated the causal link in these case reports.

56. In 2015, multiple published case reports identified additional DKA events in patients treated with SGLT-2s. These reports include:

a. Hall, *2015 -Case report of Ketoacidosis associated with Canagliflozin (Invokana).pdf*, March 5-8 ENDO CONFERENCE (2015).

b. Tomohide Hayami et al., *Case of ketoacidosis by a sodium-glucose cotransporter 2 inhibitor in a diabetic patient with a low-carbohydrate diet*, JOURNAL OF DIABETES INVESTIGATION n/a–n/a (2015).

c. Julia Hine et al., *SGLT inhibition and euglycaemic diabetic ketoacidosis*, THE LANCET DIABETES & ENDOCRINOLOGY (2015).

d. Nobuya Inagaki et al., *Efficacy and safety of canagliflozin alone or as add-on to other oral antihyperglycemic drugs in Japanese patients with type 2 diabetes: A 52-week open-label study*, 6 JOURNAL OF DIABETES INVESTIGATION 210–218 (2015).

e. Anne L. Peters et al., *Euglycemic Diabetic Ketoacidosis: A Potential Complication of Treatment With Sodium-Glucose Cotransporter 2 Inhibition*, DIABETES CARE dc150843 (2015).

f. Reginald St. Hilaire & Heather Costello, *Prescriber beware: report of adverse effect of sodium-glucose cotransporter 2 inhibitor use in a patient with contraindication*, 33 THE AMERICAN JOURNAL OF EMERGENCY MEDICINE 604.e3–604.e4 (2015).

57. Despite Defendants' knowledge of the risks of cardiovascular and ketoacidosis injuries as described above, Invokana's label fails to contain a warning for either event.

58. Along with the above described cardiovascular and ketone related injuries, SGLT-2 inhibitors, and Invokana in particular, also dramatically increase the likelihood of a patient developing kidney failure.

59. Invokana by its very mechanism of action causes dehydration and osmotic diuresis. Osmotic diuresis is the increase of urination rate caused by the presence of certain substances in the small tubes of the kidneys. The excretion occurs when substances such as glucose enter the kidney tubules and cannot be reabsorbed.

60. Because Invokana blocks sugar from being reabsorbed by the kidneys, the kidneys expel the sugar in the patient's urine. A buildup of sugar in the tubes leading from the kidneys leads to acute kidney (or "renal") failure.

61. Osmotic diuresis leads to volume depletion, which is water loss and salt loss. Volume depletion is distinct from dehydration, which relates only to water loss.

62. Volume depletion leads to decreased renal perfusion, meaning the kidneys do not push the fluid through its vessels as well as they should. Unimpeded, decreased renal perfusion leads to acute renal injury, including kidney failure which necessitates dialysis and, unencumbered, may require kidney transplants.

63. Invokana causes osmotic diuresis by forcing the kidneys to work harder and push more glucose through their tubules than the kidneys are intended to do. This continued heightened state the kidneys are put in when a patient is on Invokana makes kidney injury a higher likelihood, even for those with normal kidney function at the beginning of Invokana therapy.

64. Defendants were aware of the potential for Invokana to cause kidney failure prior to Invokana's approval. In fact, Invokana's medical review, submitted with Invokana's NDA approval documents, disclosed a nearly three-fold increase (1.7% compared to 0.6%) in acute renal failure for patients taking the higher dose of Invokana compared to those taking placebo, even in patients whose kidney function was normal.

65. Defendants knew that the likelihood of renal adverse effects such as acute renal failure was nearly tripled in patients with near normal kidney function and more than doubled in patients with even moderately impaired kidney function.

66. At the time of the FDA Advisory Committee meeting, the FDA renal review questioned Invokana's role in causing adverse events related to the kidneys when it noted "the long term renal consequences of canagliflozin's effect on the eGFR ("epidermal growth factor receptor" or the cell-surface receptor for members of the epidermal growth factor family) are unknown.…It seems prudent to assume that the volume depletion and corresponding reduction in eGFR …places patients at increased risk for clinically significant episodes of acute kidney injury."

67. Invokana's risks substantially outweigh its benefits. Usage of Invokana reduced hemoglobin A1C levels (the test by which diabetics can measure their average blood sugars over a few month time period) by only by 0.62% for the 100 mg dosage and by 0.77% for the 300 mg dosage, which published medical literature has described as a very weak reduction.

68. At all relevant times, Defendants were in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute Invokana (canagliflozin) for use as a type of prescription medication prescribed to help lower blood sugar levels in adults with diabetes mellitus Type II.

69. The weight loss they claim is a benefit is instead a byproduct of the osmotic diuresis discussed above. Put another way, the weight loss is by and large water weight, and the user is suffering from volume depletion. Once the user's fluids are corrected, their water weight comes back.

70. As part of their marketing of Invokana, Defendants widely disseminated direct-to- consumer advertising campaigns that were designed to influence patients, including

Plaintiff, to make inquiries to their prescribing physician about Invokana and/or request prescriptions for Invokana.

71. In the course of these direct to consumer advertisements, Defendants overstated the efficacy of Invokana with respect to reducing hemoglobin A1c values, failed to adequately disclose the risks of severe injuries as described herein, and misleadingly promoted Invokana for weight loss, all without disclosing potentially life-threatening and fatal consequences of which Defendants knew or should have known.

67. Further, IMSP identified 457 domestic serious adverse events with canagliflozin as the primary suspect drug for the 12 months ending with March 31, 2014. IMSP states this was a higher total than for 92% of the drugs they regularly monitor.

68. Defendants admitted they knew of these adverse events and the likelihood that Invokana would cause them. When provided an opportunity to respond to the data IMSP had collected, Janssen told IMSP that **the specific adverse effects we observed in postmarketing reports were generally consistent with those seen in clinical trials**."

69. IMSP concluded with the question of whether the "drug does more good than harm in long-term treatment." In answering this question, IMSP stated, "[T]he data were still of insufficient duration to establish whether the drug had a measurable clinical benefit on the complications of Type II diabetes. The current data are also insufficient to address unanswered questions raised in the FDA reviews about whether long-term use might result in a steady decline in kidney function, increased risk of bone fractures, or more cardiovascular events. By contrast, we observe clear evidence of harm to some patients in terms of hypersensitivity reactions and an array of renal adverse effects."

70. At all times relevant to this action, The Invokana Medication Guide, prepared and distributed by Defendants and intended for U.S. patients to whom Invokana has been prescribed, failed to warn and disclose to patients that Invokana may cause DKA, kidney failure, or cardiac events such as myocardial infarctions.

73. The Invokana used by Plaintiff was provided to her in a condition substantially the same as the condition in which it was manufactured and sold.

74. As a result of Defendants' actions, Plaintiff and her prescribing physicians were unaware, and could not reasonably have known or learned through reasonable diligence, that Plaintiff had been exposed to the risks identified herein, and that those risks were the direct and proximate result of Defendants' acts, omissions, and misrepresentations.

75. As a direct and proximate result of Defendants' negligence, wrongful conduct, and the unreasonably dangerous and defective characteristics of INVOKANA, Plaintiff suffered severe and permanent physical and emotional injuries. Plaintiff has endured pain and suffering, emotional distress, loss of enjoyment of life, and economic loss, including significant expenses for medical care and treatment which will continue in the future. Plaintiff seeks actual, compensatory, and punitive damages from Defendants.

76. Plaintiff has suffered from mental anguish from the knowledge that she may suffer life-long complications as a result of the injuries caused by INVOKANA.

77. The Defendants, their agents, servants, and/or employees, were negligent in the design, manufacture, sale, labeling, warnings, marketing, promotion, quality assurance, quality control, and distribution of Invokana in that, among other things, they:

a. Manufactured, produced, promoted, formulated, created, tested, and/or designed Invokana without thoroughly testing it and without due care;

b. Failed to analyze pre-marketing test data of Invokana;

c. Failed to conduct sufficient post-marketing and surveillance of Invokana;

d. Failed to provide adequate training and instruction to medical care providers for the appropriate use of Invokana;

e. Falsely and misleadingly over promoted, advertised and marketed Invokana as set forth herein including overstating efficacy, minimizing risk and stating that blood monitoring and dose adjustments were not necessary for safe and effective use to influence patients, such as the Plaintiff, to purchase and consume Invokana;

f. Manufacturing, producing, promoting, formulating, creating and/or designing Invokana without thoroughly testing it;

g. Manufacturing, producing, promoting, formulating, creating and/or designing Invokana without adequately testing it;

h. Not conducting sufficient testing programs to determine whether or not Invokana was safe for use; in that the Defendants herein knew or should have known that Invokana was unsafe or unfit for use by reason of the dangers to its users;

i. Selling Invokana without making proper and sufficient tests to determine the dangers to its users;

j. Negligently failing to adequately and correctly warn the Plaintiff, the Plaintiff's physicians, the public, the medical and healthcare profession, and the FDA of the dangers of Invokana;

k. Failing to provide adequate instructions regarding safety precautions to be followed by users such as the Plaintiff, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, Invokana;

l. Failing to test Invokana and/or failing to adequately, sufficiently and properly test Invokana;

m. Negligently advertising and recommending the use of Invokana without sufficient knowledge as to its dangerous propensities;

n. Negligently representing that Invokana was safe for use for its intended purpose, when, in fact, it was unsafe;

o. Negligently designing Invokana in a manner which was dangerous to its users;

p. Negligently manufacturing Invokana in a manner which was dangerous to users;

q. Negligently producing Invokana in a manner which was dangerous to its users;

r. Negligently assembling Invokana in a manner which was dangerous to its users;

s. Concealing information from the Plaintiff and the public, in knowing that Invokana was unsafe, dangerous, and/or non-conforming with FDA regulations;

t. Placing an unsafe product into the stream of commerce.

78. By reason of the foregoing, Plaintiff has been severely and permanently injured, and will require more constant and continuous medical monitoring and treatment than prior to Plaintiff's use of Defendants' drug, Invokana.

79. Plaintiff's use of Invokana caused Plaintiff to suffer serious and life threatening injuries as detailed below.

COUNT I

DESIGN DEFECT UNDER LA. R.S. 9:2800.56

80. Plaintiff restates the allegations set forth above as if fully rewritten herein.

81. INVOKANA is defective in its design or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation. The subject product was unreasonably dangerous in design.

82. The subject product was unreasonably dangerous in design as provided by La. R.S. 9:2800.56.

83. At all times material to this action, INVOKANA was expected to reach, and did reach, consumers in the State of Louisiana and throughout the United States, including Plaintiff, without substantial change in the condition in which it was sold.

84. At all times material to this action, INVOKANA was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following:

a. When placed in the stream of commerce, INVOKANA contained

unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiff to risks that exceeded the benefits of the subject product, including, but not limited to, permanent personal injuries including, but not limited to, developing diabetic ketoacidosis, stroke, heart attack, severe kidney damage, and other serious injuries and side effects;

b. When placed in the stream of commerce, INVOKANA was defective in design and formulation, making the use of INVOKANA more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other medications and similar drugs on the market to treat type 2 diabetes;

c. The design defects of INVOKANA existed before it left the control of Defendants;

d. INVOKANA was insufficiently and inadequately tested;

e. INVOKANA caused harmful side effects that outweighed any potential utility; and

f. INVOKANA was not accompanied by adequate instructions and/or warnings to fully apprise consumers, including Plaintiff, of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendants liable to Plaintiff.

85. Defendants were aware at the time Invokana was marketed that ingestion of Invokana would result in an increased risk of kidney failure and other injuries.

86. The Defendants, who designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold Invokana in the formulation developed were aware that it posed a greater likelihood of injury than other diabetic drugs, including Metformin and Glimipiride, and was also more dangerous than an ordinary consumer could reasonably foresee or anticipate.

87. The harm caused by Invokana far outweighed any benefit derived, rendering Invokana more dangerous than alternative products.

88. Defendants could have designed Invokana to make it less dangerous. When defendants designed Invokana, the state of the industry's scientific knowledge was such that a less risky design was attainable.

89. At the time Invokana left Defendants' control, there was a practical, technically feasible and safer alternative design that would have prevented the harm Plaintiff suffered which was reasonably anticipated via the intended function of Invokana.

90. This safer alternative was demonstrated by the existence of other diabetes medications which had a more established safety profile and a considerably lower risk profile.

91. In addition, at the time the subject product left the control of the Defendants, there were practical and feasible alternative drugs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the product. These safer alternatives were economically and technologically feasible, and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the product's utility.

92. Plaintiff was prescribed, purchased, and used INVOKANA. Plaintiff used Invokana for its intended purpose and in the manner recommended, promoted, marketed, and reasonably anticipated by Defendants.

93. The likelihood that Invokana's design would cause the Plaintiff's damage and the gravity of that damage outweighed the burden on Defendants of adopting such alternative design(s) and the adverse effects of such alternative design(s) on the utility of the product.

COUNT II

INADEQUATE WARNING UNDER LA. R.S. 9:2800.57

94. Plaintiff restates the allegations set forth above as if fully rewritten herein.

95. INVOKANA was defective and unreasonably dangerous when it left the possession of Defendants in that it contained warnings insufficient to alert consumers, including Plaintiff, of the dangerous risks and reactions associated with the subject product, including but not limited to its propensity to permanent physical injuries including, but not limited to, developing diabetic ketoacidosis, stroke, heart attack, severe kidney damage, and other serious injuries, side effects, and death; notwithstanding Defendants' knowledge of an increased risk of these injuries and side effects over other forms of treatment for type 2 diabetes. Thus, the subject product was unreasonably dangerous because an adequate warning was not provided.

96. The subject product manufactured and supplied by Defendants was defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of serious bodily harm from the use of the subject product, Defendants failed to provide an adequate warning to consumers and/or their health care providers of the defects of the product, and/or alternatively failed to conform to federal and/or state requirements for labeling, warnings and instructions, or recall, while knowing that the

product could cause serious injury and/or death.

97. Plaintiff was prescribed and used the subject product for its intended purpose.

98. Plaintiff could not have discovered any defect in the subject product through the exercise of reasonable care.

99. Defendants, as manufacturers and/or distributors of the subject prescription product, are held to the level of knowledge of an expert in the field.

100. Defendants, the manufacturers and/or distributors of the subject prescription product, are held to a level of knowledge of an expert in the field as the Reference Listed Drug Company and the New Drug Application Holder.

101. The warnings that were given by Defendants were not accurate, clear, and/or ambiguous.

102. The warnings that were given by Defendants failed to properly warn physicians of the increased risks of permanent physical injuries including, but not limited to, diabetic ketoacidosis, stroke, heart attack, and severe kidney damage.

103. Plaintiff, individually and through her prescribing physician, reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

104. Defendants had a continuing duty to warn Plaintiff of the dangers associated with the subject product.

105. Furthermore, Defendants:

a. disseminated information that was inaccurate, false and misleading, and which failed to communicate accurately or adequately the comparative severity, duration, and extent of the risk of injury with the use of Invokana;

b. continue to aggressively promote Invokana even after Defendants knew or should have known of the unreasonable risk from use;

c. failed to accompany their product with proper or adequate warning or labeling regarding adverse side effects and health risk associated with the use of Invokana and the comparative severity of such adverse effects;

d. failed to provide warnings, instructions or other information accurately reflected the symptoms, scope and severity of the side effects and health risks including but not limited to those associated with the severity of Invokana's effect on acid – base balance; and

e. overwhelmed, downplayed and or otherwise suppressed through aggressive marketing and promotion the risks associated with the use of Invokana.

106. Had Plaintiff received adequate warnings regarding the risks of the subject product, she would not have used it.

107. Despite the fact that the Defendants knew or should have known that Invokana caused unreasonable, dangerous side effects which many users would be unable to remedy by any means, the Defendants continued to market Invokana to consumers, including the Plaintiff, the and the medical community.

108. The Defendants knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury such as kidney failure as a result of the Defendants' failure to exercise ordinary care, as set forth above.

109. It was foreseeable that Defendants' product, Invokana, as designed, would cause serious injury such as kidney failure to consumers, including the Plaintiff.

110. As a direct and proximate result of the Defendants' aforesaid actions

and negligence, the Plaintiff suffered serious and dangerous side effects including life-threatening conditions, as well as other severe and personal injuries such as kidney failure which were permanent and lasting in nature, physical pain and mental anguish, including, but not limited to, diminished enjoyment of life, shortened life expectancy, expenses for hospitalization and medical treatment, and any and all damages that are reasonable in the premises.

111. The Defendants' conduct was extreme and outrageous. The Defendants risked the lives of consumers and users of their products, including the Plaintiff, with the knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. The Defendants made conscious decisions not to re-design, re-label, warn or inform the unsuspecting consuming public.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment against each of the Defendants, and each of them individually, jointly, and severally, as follows:

1. Compensatory damages in excess of the jurisdictional amount, including but not limited to, non-economic damages in excess of $75,000.

2. Medical expenses and other economic damages in an amount to be determined at trial of this action;

3. Pain and suffering;

4. Non-economic damages for an increased risk of future complications as a direct result of plaintiff's injury;

5. Prejudgment interest at the highest lawful rate allowed by law;

6. Interest on the judgment at the highest legal rate from the date of judgment until collected;

7. Attorneys' fees, expenses, and costs of this action; and

8. Such further relief as this Court deems necessary, just and proper.

JURY DEMAND

Plaintiff hereby demands a trial by jury as to all issues so triable.

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF LOUISIANA
SHREVEPORT DIVISION

AMBER RUTLAND,

Plaintiff,

v.

JANSSEN PHARMACEUTICALS, INC. and JOHNSON & JOHNSON CO.

Defendants.

Civil Action No. 5:16-cv-666

JUDGE MAURICE HICKS, JR.

MAGISTRATE JUDGE KAREN HAYES

CERTIFICATE OF SERVICE

I hereby certify that on October 11, 2016, the foregoing pleading was filed electronically with the Clerk of Court using the CM/ECF system. Notice of this filing will be sent to counsel for Defendants by operation of the Court's electronic filing system.

/s/ Lionel H. Sutton, III
Lionel H. Sutton, III, Esq. (20386)